



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service  
Food and Drug Administration  
Central Region

95126d

Telephone (973)

526-6008

New Jersey District  
Waterview Corporate Center  
10 Waterview Blvd., 3<sup>rd</sup> Floor  
Parsippany, NJ 07054

**WARNING LETTER**

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

December 2, 2004

File # 05 -NWJ-04

Mr. Francis S. Key  
Owner  
Purest Colloids, Inc.  
231 Irick Road  
Westampton, NJ 08060

Dear Mr. Key:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.purestcolloids.com>. This review found violations of the Federal Food, Drug, and Cosmetic Act (the Act) in the promotion of your products Mesosilver<sup>™</sup>, Mesogold<sup>™</sup>, and Mesocopper<sup>™</sup>. You can find the Act and FDA regulations through links on FDA's Internet home page at: <http://www.fda.gov>.

Mesosilver<sup>™</sup>, Mesogold<sup>™</sup>, and Mesocopper<sup>™</sup> are promoted on your website for conditions that cause the products to be drugs under section 201(g)(1) of the Act [21 USC 321(g)(1)]. The therapeutic claims on your web site establish that the products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of these products with these claims violates the Act. We further note that our investigator provided you with a copy of this section of the Act and discussed the differences between dietary supplements and drugs with you during our inspection of March 29, 30 and April 5, 2004.

Examples of some of the claims observed on your web site include:

### **Mesosilver™**

“[S]ilver promotes the production of new cells, thus increasing the rate of wound healing.”

“[R]ecognized as one of the most potent antidotes for food poisoning”

“[C]olloidal silver is known to be effective against multiple disease- causing pathogenic organisms, including anthrax, diphtheria, influenza, whooping cough and typhoid.”

“Colloidal Silver appears to be nature’s most powerful antibiotic.”

### **Mesogold™**

“Word of gold’s power to relieve the pain of arthritis was passed down through the centuries and even today it is used in the treatment of rheumatoid arthritis, its efficacy confirmed by modern medical research.”

“...Colloidal Gold was listed as the number one remedy against obesity.”

“One experimental new gold compound blocks virus replication in infected cells and is being tested for the treatment of AIDS.”

“[U]sed to ...treat unstable mental and emotional states such as depression...suicidal tendencies, seasonal affective disorder (S.A.D.)....

“Other traditional treatments include arthritis, obesity, skin ulcers, puncture wounds, nerve damage (neuropathy) ... hyperactivity.... It is also used to alleviate the wasting and malnutrition associated with chronic diseases.”

### **Mesocopper™**

“A variety of inorganic copper preparations were found to be effective in treating chronic adenitis, eczema, impetigo, scrophulosis, tubercular infections, lupus, syphilis, anemias, chorea and facial neuralgia.”

“...subcutaneous and intravenous injections of...colloidal copper softened and degenerated carcinomas transplanted into mice.”

“Injections of colloidal copper mobilized and expelled tumor tissue.”

Purest Colloids, Inc.  
Westampton, NJ  
Warning Letter 05-NWJ-04  
December 2, 2004  
Page 3 of 5

"[C]opper complexes have therapeutic benefit in the treatment of inflammatory diseases. Copper complexes have ... been used successfully to treat patients with arthritis and other chronic degenerative diseases."

"[S]tudies suggest the use of copper dietary supplements as a means of preventing and controlling diseases such as atherosclerosis...coronary heart disease, aortic aneurysms and myocardial infarction."

"[C]opper metallo-organic complexes have been shown to have radiation protection and radiation recovery activities from ionizing radiation such as that used in cancer treatments.... Since these complexes may also have anticarcinogenic activity, there may be merit in using copper complexes in the treatment of cancer and in particular, treating patients undergoing ...radiation therapy...."

Furthermore, your products are not generally recognized as safe and effective for the above referenced conditions and therefore, the products are "new drugs" under section 201(p) of the Act [21 USC 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 USC 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective. Mesosilver™, Mesogold™, and Mesocopper™ are also misbranded because their labeling fails to bear adequate directions for the conditions for which they are offered [section 502(f)(1) of the Act].

The above is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations. You also have a responsibility to prevent further violations of the Act and all applicable regulations.

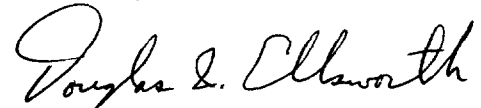
Failure to promptly correct these violations may result in regulatory action without further notice. For instance, we may take further action to seize your product(s) and/ or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific steps that you have taken to correct the violations described above and to assure that similar violations do not occur. Your response should include an explanation of each step being taken to correct the violations and prevent a reoccurrence. You may wish to include in your response documentation concerning procedures you have implemented or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when the corrections will be completed.

Purest Colloids, Inc.  
Westampton, NJ  
Warning Letter 05-NWJ-04  
December 2, 2004  
Page 4 of 5

Your response to this letter should be directed to the U.S. Food and Drug Administration, Attention: Richard D. Manney, Compliance Officer, at the address and telephone number listed above. If you have questions regarding this letter, please contact Mr. Manney directly.

Sincerely,

A handwritten signature in cursive script, reading "Douglas I. Ellsworth". The signature is written in dark ink and is positioned above the printed name and title.

Douglas I. Ellsworth  
District Director  
New Jersey District